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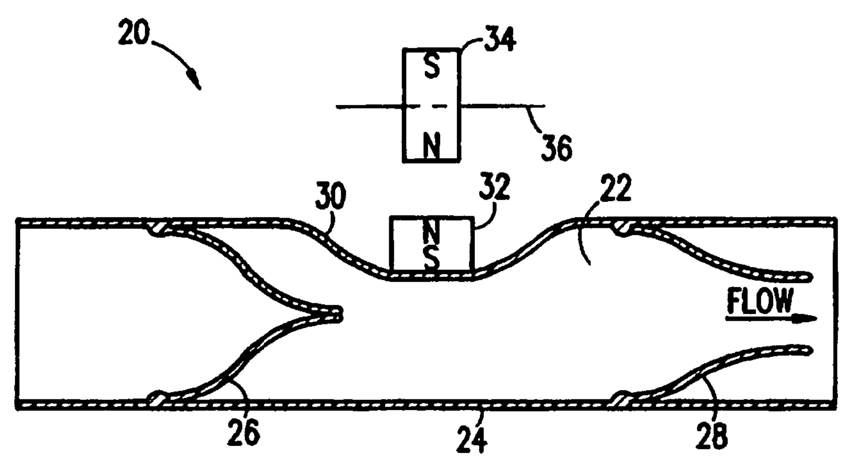

(57) Abstract

Pump apparatus operated by remote energy transfer, for implantation in the body of a subject. The apparatus includes a pump chamber having an inlet and an outlet, and comprising an exterior wall, which defines and contains a volume of a fluid therein. The chamber has a one-way inlet valve at the inlet thereof and a one-way outlet valve at the outlet. A magnetic field-responsive element is coupled to the chamber, such that movement of the element in response to application of a magnetic field thereto causes the volume of fluid in the chamber to change.

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IMPLANTABLE PUMP AND PROSTHETIC DEVICES

FIELD OF THE INVENTION

The present invention relates generally to implantable medical devices, and specifically to implantable pumps operated by remote energy transfer.

BACKGROUND OF THE INVENTION

Implantable pumps are well-known in the art for various medical applications. Such pumps generally require energy to be transferred from outside the body in order to power them. For example, the Dynaflex inflatable penile prosthesis, manufactured by American Medical Systems Inc., includes a pump for transferring water from a low-pressure reservoir to a high-pressure reservoir, implanted in the penis of a subject, to produce an erection. The pump is actuated by manual pressure thereon, exerted through the skin of the subject. Such pressure can be difficult to exert in the proper manner, and can cause discomfort and pain.

Similarly, the AMS 800 urinary sphincter, produced by the same manufacturer, includes a periurethral inflatable cuff, used to overcome urinary incontinence when the function of the natural sphincter is impaired. The cuff is coupled to a manually-operated pump and a pressure regulator chamber, which are implanted in a patient's body together with the cuff. The cuff is maintained at a constant pressure of 60-80 cm of water, which is generally higher than the bladder pressure. To urinate, the patient releases the pressure in the cuff by pressing on the implanted pump, which pumps the fluid out of the cuff to the chamber. Aspects of this system are described in U.S. patent 4,222,377, whose disclosure is incorporated herein by reference.

This artificial sphincter has several shortcomings, however. The constant concentric pressure that the periurethral cuff exerts on the urethra results in impaired blood supply to tissue in the area, leading to tissue atrophy, urethral erosion and infection. Furthermore, the constant pressure in the cuff is not always sufficient to overcome transient increases in bladder pressure that may result from straining, coughing, laughing or contraction of the detrusor muscle, for example. In such cases, urine leakage may result.

U.S. patents 4,571,749 and 4,731,083, whose disclosures are incorporated herein by reference, describe an artificial sphincter device whose pressure can vary in response to changes in abdominal or intravesical (bladder) pressure. The device includes a periurethral cuff with subdermal pump and pressure regulator, with the addition of a hydraulic pressure sensor. This system is complicated, however, and requires manual manipulation of the subdermal pump and cuff control.

The use of magnetic energy to drive implantable pumps is similarly well-known in the art. Exemplary patents in this regard include U.S. patents 4,941,461 and 5,4337,605, which are incorporated herein by reference. These patents describe implantable pumps including metal elements, such as coils, which receive energy inductively from electromagnetic activators outside the body. The inductively transferred electromagnetic energy is converted into mechanical

energy, to power the pumps. Because they involve multiple stages of energy transfer and conversion, such devices tend to be bulky, stiff and inefficient, and the metal elements present problems of biocompatibility.

PCT patent publication WO95/29716, which is incorporated herein by reference, describes rotary implantable vane pumps and valves. These devices are operated by placing a rotating drive magnet in a suitable location outside the body, to drive a counter-rotating driven magnet, which is coupled to a rotating pump and/or valve mechanism. Since the driven magnet must be rotatably mounted and reliably coupled to the pump and/or valve mechanism, these devices also tend to be inherently stiff, limiting their usefulness in certain implantable devices such as penile prostheses and urinary sphincters.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide compact implantable pumps, operated by remote transfer of magnetic energy.

In one aspect of the present invention, the implantable pumps include miniature, flexible pump chambers.

In another aspect of the present invention, an implantable pump cooperates with a valve, which is similarly operated by remote energy transfer.

In one aspect of the present invention, an implantable pump is used in a penile prosthesis.

In another aspect of the present invention, an implantable pump is used in a prosthetic urinary sphincter, which has the further advantage of increasing and decreasing pressure on the urethra in response to changes in intra-abdominal or intravesical pressure.

In some preferred embodiments of the present invention, an implantable pump comprises a miniature chamber, having one-way inlet and outlet valves so that a fluid can flow therethrough only in a desired direction. A magnetic field-responsive element is coupled to the chamber, in such manner that application of a suitable time-varying external magnetic field, exerting an oscillatory force on the element, causes the volume of the chamber alternately to increase, drawing fluid thereinto, and to decrease, expelling fluid therefrom. Thus, the fluid is pumped through the chamber in the desired direction.

The term "fluid" as used herein includes any suitable type of liquid or gas, including water, physiological solutions, blood, urine, air, carbon dioxide or the like.

Preferably, the inlet and outlet valves comprise leaflet valves, as are known in the art, which are positioned at opposite ends of the chamber, defining a flow axis therethrough. Alternatively, the inlet and outlet valves may comprise any type of suitable one-way valves known in the art.

In other preferred embodiments of the present invention, an implantable pump assembly comprises a magnetically-driven rotary pump. Preferably, the pump comprises a miniature turbine pump, driven by sequential pole coupling, as described in the above-mentioned PCT patent publication WO95/29716. Alternatively, the pump may comprise a centrifugal pump or

another suitable rotary pump of any type known in the art. The pump assembly further comprises a valve, preferably in series with the pump. The valve is coupled to the pump such that the valve is opened and closed by rotational motion of the pump, responsive to an external magnetic field. The valve is operated by energy transfer from the pump, preferably by mechanical coupling of energy from the pump or, alternatively, by electrical energy transfer or by any other suitable method of energy transfer known in the art.

In some preferred embodiments of the present invention, the pump communicates at an inlet end thereof with a low-pressure reservoir, and with a high-pressure reservoir at an outlet end of the pump. When the pump is activated, it transfers fluid from the low-pressure reservoir to inflate the high-pressure reservoir.

In some of these preferred embodiments, the high-pressure reservoir is flexible when deflated, and becomes rigid when inflated. In one such preferred embodiment, the high-pressure chamber is implanted as a penile prosthesis, which creates a penile erection when inflated.

In other preferred embodiments of the present invention, the pump is a part of an implantable artificial sphincter assembly. Preferably, the sphincter assembly comprises an inflatable periurethral cuff and an intra-abdominal pressure regulator chamber, both filled with a fluid and mutually connected by a tube of sufficiently large diameter to maintain the cuff and the chamber at substantially equal fluid pressures. The pump is connected between the cuff and the chamber, such that the inlet of the pump communicates with the cuff, and the outlet of the pump communicates with the chamber. Preferably, the pump is connected in series with the large-diameter tube and with a valve, preferably coupled to the pump so as to be opened and closed by the motion of the pump, as described above, thereby controlling the flow of the fluid through the tube. Alternatively, the pump may be connected in a shunt configuration, in parallel with the large-diameter tube and with a valve in series with the tube. The entire assembly is implanted in the abdomen of a subject, with the periurethral cuff surrounding the subject's urethra.

Normally, to maintain urinary continence, the valve is kept open, and the pump does not operate, so that the fluid pressure in the cuff causes the cuff to squeeze inward on the urethra, preventing urinary flow. If the intra-abdominal or intravesicular pressure rises, for example, when the subject strains or laughs, this pressure rise causes a concomitant pressure increase in the pressure regulator chamber and, consequently, in the cuff as well, so that urine is prevented from leaking through the sphincter.

When the subject wishes to urinate, however, he or she actuates the pump, so as to pump fluid out of the cuff and into the chamber, thereby reducing the pressure in the cuff and allowing urine to pass therethrough. In preferred embodiments in which the pump is connected in parallel with the tube, the valve is closed during pumping, to prevent fluid returning to the cuff. In preferred embodiments in which the pump is in series with the tube, the valve is kept open during pumping, but may be closed thereafter to keep the cuff deflated. Preferably, the pump is actuated using a magnetic actuator as will be described below. The valve may be of a type that

is actuated manually, as is known in the art, or preferably, by a magnetically-driven mechanism, either coupled to the pump, as described above, or of any other suitable type, for example, as described in the above-mentioned PCT patent publication WO95/29716.

In some preferred embodiments of the present invention, wherein the implantable pump comprises a miniature chamber having one-way inlet and outlet valves, as described above, the chamber comprises an exterior wall, substantially surrounding and defining the volume of the chamber, at least a portion of which wall is flexible. Preferably the magnetic field-responsive element is coupled to this flexible portion of the wall, so that when the time-varying magnetic field is applied, the element causes the flexible portion to flex alternately inward and outward, thereby decreasing and increasing the volume of the chamber and thus pumping fluid therethrough.

In some of these preferred embodiments of the present invention, the wall, or at least the flexible portion thereof, is resilient, such that when it is deformed, it tends to spring back to its original shape with a characteristic, resonant frequency of mechanical oscillation. Preferably, the time-varying magnetic field oscillates at a frequency that is generally equal to the resonant frequency of the wall. As a result, the flexing motion of the wall due to the force exerted on the magnetic field-responsive element by the oscillating magnetic field will be mechanically amplified, so that the relative increase and decrease of the volume of the chamber with each oscillation will be substantially increased.

In one such preferred embodiment of the present invention, the magnetic field-responsive element comprises a magnetostrictive material, as is known in the art, preferably in the shape of a ring, circumferentially substantially surrounding a portion of the chamber that includes the flexible portion of the wall. Application of the time-varying magnetic field causes the ring to alternately constrict and expand, thereby decreasing and increasing the volume of the chamber.

In other preferred embodiments of the present invention, the chamber is generally tubular, comprising a sleeve closed at both ends and thus defining the volume of the chamber, wherein one of the ends is closed by a movable plug, to which the magnetic field-responsive element is coupled. Preferably, the element is substantially contained within the plug. The plug is preferably held in the sleeve in such manner as to translate axially back and forth over a desired, predetermined range while substantially maintaining a fluid seal with an inner surface surrounding the plug. Thus, when the time-varying magnetic field is applied, the element causes the plug to move alternately back and forth in the sleeve, thereby decreasing and increasing the volume of the chamber.

In some such preferred embodiments of the present invention, the plug further includes one of the valves, i.e., either the inlet valve or the outlet valve.

Moreover, in some of these preferred embodiments of the present invention, the plug is held in the sleeve by a resilient coupling element, such as an elastic rubber diaphragm. Preferably, the resilient coupling element has a resonant mechanical frequency, and the time-

varying magnetic field oscillates substantially at this frequency, so that the motion of the plug is amplified, as described above.

Preferably, the magnetic field-responsive element comprises a biocompatible ferromagnetic material, known in the art, such as an alloy of palladium, platinum, cobalt and gallium, or alternatively, an alloy of cobalt, nickel, chromium and molybdenum. Alternatively, the magnetic field-responsive element comprises a magnet, preferably made of neodymium iron boron or samarium cobalt, and coated with a biocompatible coating.

In still other preferred embodiments of the present invention, the magnetic field-responsive element comprises a coil of non-magnetic, conductive wire. Application of the time-varying magnetic field causes an electrical current to flow in the coil, by electromagnetic induction. The current flowing in the coil, in turn, generates an induced magnetic field, which interacts with the applied magnetic field to exert the oscillatory force on the element that drives the pump.

Some preferred embodiments of the present invention include a magnetic drive unit, which produces the time-varying magnetic field to drive the pump. In one such preferred embodiment, the drive unit comprises a horseshoe magnet, which rotates about its axis of symmetry to produce a circularly-oscillating magnetic field in the vicinity of its poles. Alternatively, the drive unit may comprise a rotating or oscillating bar magnet, or other type of rotating or oscillating magnet known in the art.

In other such preferred embodiments, the magnetic drive unit comprises an electromagnet, preferably comprising a coil, which is driven with an alternating current, at a desired frequency, to produce an oscillatory magnet field.

In other preferred embodiments of the present invention, the magnetic field-responsive element comprises a rotating magnet within a conducting coil, which functions as a miniature electrical generator, to produce electrical power in response to the time-varying magnetic field. This electrical power is preferably used to operate a valve coupled to the pump, as described above. Alternatively, the power may be used to drive a piezoelectric crystal, coupled to the pump chamber as described above. Expansion and contraction of the crystal, in response to a voltage applied thereto, causes the volume of the chamber to alternately increase and decrease, as described above.

Further alternatively, the electrical current may be used to induce a phase change in a liquid contained in a miniature reservoir coupled to the pump chamber, for example by heating the liquid. The phase change causes at least a portion of the liquid to form an expanding vapor bubble, thus creating a pressure which exerts force on the pump chamber, decreasing its volume.

Although the above preferred embodiments are described in terms of magnetically-driven pumps, it will be appreciated that some of the principles of the present invention may similarly be applied to miniature, implantable pumps driven by other forms of energy.

There is therefore provided, in accordance with a preferred embodiment of the present invention, pump apparatus operated by remote energy transfer, for implantation in the body of a subject, the apparatus including:

a pump chamber having an inlet and an outlet, and including an exterior wall, which defines and contains a volume of a fluid therein;

a one-way inlet valve at the inlet of the chamber;

a one-way outlet valve at the outlet of the chamber; and

a magnetic field-responsive element, coupled to the chamber, such that movement of the element in response to application of a magnetic field thereto causes the volume of fluid in the chamber to change.

Preferably, movement of the element in a first direction causes the volume to increase, and movement of the element in a second direction, generally opposite to the first direction, causes the volume to decrease. More preferably, movement of the element in the first direction causes the inlet valve to open and the outlet valve to close, so that fluid flows into the chamber, and movement of the element in the second direction causes the inlet valve to close and the outlet valve to open, so that fluid flows out of the chamber.

Preferably, the inlet and outlet valves include leaflet valves.

Preferably, the apparatus has a resonant mechanical frequency with respect to movement of the element, and the element includes a magnetic field-responsive circuit having a resonant oscillation frequency approximately equal to half the resonant mechanical frequency.

Further preferably, the wall includes resilient material, and at least a portion of the wall flexes in response to movement of the element.

In a preferred embodiment of the invention, the chamber is generally tubular in form, having an axis generally defined by the long dimension of the chamber, with the inlet and outlet valves disposed axially at opposite ends of the chamber, and wherein the element is coupled radially to the portion of the wall that flexes. Preferably, in response to application of the magnetic field to the element in a first field direction, which is preferably generally perpendicular to the axis of the chamber, the element causes the portion of the wall to flex radially outward, and in response to application of the magnetic field in a second field direction, generally opposite to the first field direction, the element causes the portion of the wall to flex radially inward.

In another preferred embodiment of the invention, the wall of the chamber includes a generally tubular sleeve, having an axis generally defined by the long dimension of the sleeve, one of the ends of which is closed by an axially movable plug, to which the element is coupled. Preferably, the element is contained in the plug.

Additionally or alternatively, the plug contains at least one of the inlet and outlet valves.

Preferably, the plug is coupled to the sleeve by an elastic mounting member. Further preferably, in response to application of the magnetic field to the element in a first field direction, preferably generally parallel to the axis of the sleeve, the element causes the plug to move axially

outward, and in response to application of the magnetic field in a second field direction, generally opposite to the first field direction, the element causes the plug to move axially inward.

Preferably, the element includes a conductive coil.

Alternatively, the element includes a permanent magnet or, further alternatively, ferromagnetic material.

Additionally or alternatively, the element includes magnetostrictive material.

There is further provided, in accordance with a preferred embodiment of the present invention, pump apparatus operated by remote energy transfer, for implantation in the body of a subject, the apparatus including:

a pump chamber having an inlet and an outlet;

a pump mechanism within the chamber, which pumps a fluid from the inlet to the outlet;

a magnetic field-responsive element, coupled to drive the pump mechanism responsive to application of a magnetic field thereto; and

a valve, which is driven by the pump mechanism to control the flow of the fluid through the pump chamber.

Preferably, the magnetic field-responsive element includes a magnet driven by the magnetic field by sequential pole coupling.

Preferably, the pump mechanism includes a rotary mechanism, most preferably a turbine pump, or alternatively, a centrifugal pump.

Preferably, the valve is mechanically coupled to the pump mechanism. Preferably, the pump mechanism includes a rotary shaft having a longitudinal axis, and wherein the valve includes a plug, which moves longitudinally along the axis to open and close a valve opening, responsive to rotation of the shaft.

In a preferred embodiment of the invention, the plug is coupled to an inertial element, which is coupled to the shaft so as to rotate thereabout. Preferably, the shaft includes a threaded portion, and wherein the inertial element includes a nut, which travels longitudinally along the threaded portion of the shaft.

Preferably, the apparatus includes a stop, which stops the travel of the nut in at least one of a closed and an open position of the valve.

Alternatively, the valve is electrically coupled to the pump mechanism. Preferably, the apparatus includes a generating coil associated with the magnetic field-responsive element, which generates an electrical current for operating the valve. Preferably, a rectifier rectifies the current generated by the generating coil.

In a preferred embodiment of the invention, the valve includes an electromagnet, which is powered by the electrical current generated by the generating coil. Preferably, the valve includes an opening and a plug received by the opening, and the plug includes a magnetic material, such that the valve opens and closes by movement of the plug relative to the opening, responsive to a magnetic field produced by the electromagnet. More preferably, the magnetic material, most

preferably including silicon steel, is magnetized and demagnetized by the magnetic field produced by the electromagnet.

Preferably, the electromagnet includes a ferromagnetic core, and the valve opens and closes responsive to the direction of flow of an electrical current in the coil. Preferably, the direction of flow of the current in the coil is switched responsive to a change in a speed of movement of the magnetic field-responsive element.

In a preferred embodiment of the invention, the apparatus includes a hand-held magnetic actuator, preferably including a rotating magnet, which generates a time-varying magnetic field outside the body. Preferably, the rotating magnet defines a plane and rotates about an axis substantially parallel to the plane and passing between the poles of the rotating magnet.

Alternatively, the actuator includes an electromagnet.

In a preferred embodiment of the invention, the apparatus includes a low-pressure reservoir communicating with the inlet of the pump chamber and a high-pressure reservoir communicating with the outlet of the pump chamber, wherein the apparatus transfers fluid from the low-pressure to the high-pressure reservoir, preferably inflating the high-pressure reservoir.

In one such preferred embodiment, the high-pressure reservoir is implanted in the penis of a subject, and wherein inflation of the reservoir causes it to become rigid, thereby producing an erection of the penis.

In another preferred embodiment, the apparatus is implanted in the abdomen of a subject and includes:

a cuff, filled with a fluid, communicating with the inlet of the pump chamber, which cuff substantially surrounds the urethra; and

a pressure-responsive regulator chamber, communicating with the outlet of the pump chamber,

wherein pressure of the fluid in the cuff restricts urinary flow through the urethra, and

wherein the pump operates to transfer the fluid from the cuff to the chamber, such that the pressure exerted by the cuff on the urethra decreases, allowing urine to flow through the urethra.

There is also provided, in accordance with a preferred embodiment of the present invention, an artificial urinary sphincter for implantation in the abdomen of a subject, to control urinary flow through the subject's urethra, including:

a cuff, filled with a fluid, which cuff substantially surrounds and exerts pressure on the urethra, so as to restrict urinary flow therethrough;

a tube, containing a valve and having first and second ends, wherein the first end is in fluid communication with the cuff;

a pressure-responsive regulator chamber, in fluid communication with the second end of the tube, such that when the valve is open, pressure exerted on the chamber causes a corresponding pressure to be exerted by the cuff on the urethra; and

a miniature pump, connected between the cuff and the regulator chamber, so as to pump the fluid from the cuff to the chamber, in order to reduce the pressure exerted by the cuff and allow urine to pass through the urethra.

Preferably, the pump is actuated by a magnetic field produced outside the subject's body.

Preferably, the pump and the valve are connected between the cuff and the chamber in parallel, or alternatively, in series.

Preferably, when the pump is not operating, the cuff and the regulator chamber are maintained at substantially equal pressures by fluid flow therebetweeen, and the pressures in the regulator chamber and the cuff increase responsive to an increase in pressure in the subject's bladder.

There is moreover provided, in accordance with a preferred embodiment of the present invention, a method for pumping a fluid from a source location to a receiving location inside the body of a subject, the method including:

coupling a magnetic field-responsive element to an implantable pump chamber characterized by a variable volume and having one-way inlet and outlet valves, so that oscillatory movement of the element causes the volume of the chamber to alternately increase and decrease;

implanting the chamber and the element inside the body, wherein the inlet and outlet valves are in fluid communication with the source and receiving locations, respectively; and

applying a cyclically time-varying magnetic field to the element, causing oscillatory movement of the element, which causes the fluid to be pumped through the chamber from the source to the receiving location.

Preferably, the chamber and the element are jointly characterized by a resonant frequency, and applying the magnetic field to the element includes applying an oscillatory magnetic field having an oscillation frequency that is substantially dependent on the resonant frequency, most preferably generally equal to the resonant frequency, or alternatively, generally equal to half the resonant frequency.

Preferably, applying the cyclically varying magnetic field includes alternately applying the field in a first direction, which causes the volume of the chamber to increase, so that fluid is drawn into the chamber through the inlet valve, and applying the field in a second direction, generally opposite to the first direction, which causes the volume of the chamber to decrease, so that fluid is ejected from the chamber through the outlet valve.

Preferably, the pump chamber has an axis defined by a long dimension thereof, and the first and second directions are generally parallel to the axis or alternatively, generally perpendicular to the axis.

There is further provided, in accordance with a preferred embodiment of the present invention, a method for pumping a fluid from a source location to a receiving location inside the body of a subject, the method including:

coupling a magnetic field-responsive element to a rotary pump mechanism in an implantable pump chamber having an inlet and an outlet, so that rotation of the element causes the fluid to be pumped through the chamber;

coupling a valve to the pump mechanism so as to open and close responsive to energy received by the valve from the pump mechanism;

implanting the chamber inside the body, such that the inlet and outlet are in fluid communication with the source and receiving locations, respectively; and

applying a cyclically time-varying magnetic field to the element, causing rotation of the element, which opens the valve and causes the fluid to be pumped through the chamber from the source to the receiving location.

Preferably, the method includes altering the time-varying magnetic field applied to the element, causing a change in the rotation of the element, most preferably stopping the rotation by removing the time-varying magnetic field applied to the element, which closes the valve.

Preferably, coupling the valve to the pump mechanism includes mechanically coupling the valve to the pump mechanism, or alternatively, electrically coupling the valve to the pump mechanism.

Preferably, applying the magnetic field includes rotating a magnet about an axis passing between north and south poles thereof, and bringing the magnet into proximity with the element.

Alternatively, applying the magnetic field includes applying an oscillatory electrical current to a coil, and bringing the coil into proximity with the element.

There is also provided, in accordance with a preferred embodiment of the present invention, a method for treatment of urinary incontinence in a subject, including:

coupling an fluid-filled cuff to a pressure-responsive chamber;

connecting a miniature pump between the cuff and the chamber, so that when the pump is actuated, it pumps fluid from the cuff to the chamber;

implanting the cuff around the urethra of the subject, so as to exert pressure on the urethra and thus restrict urine flow therethrough;

implanting the chamber and pump in the abdomen of the patient, with the chamber adjacent to the urinary bladder, such that the pressure in the chamber increases in response to a transient increase in pressure in the bladder, causing fluid to flow from the chamber, through the tube and into the cuff, thus increasing the pressure exerted by the cuff on the urethra, so as to prevent leakage of urine through the urethra; and

actuating the pump to reduce the pressure in the cuff and thus to allow urination.

Preferably, the pump includes a magnetic-field responsive element, and actuating the pump includes applying a magnetic field outside the body of the subject, so as to transfer energy to the magnetic-field responsive element.

Preferably, a valve is closed between the chamber and the cuff, so as to prevent the flow of fluid from the chamber to the cuff.

Preferably, connecting the pump includes connecting the pump in a shunt configuration with respect to the valve or alternatively, in series with the valve.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A and 1B are schematic, sectional illustrations of a miniature implantable pump, at two different, respective points in a pump cycle thereof, in accordance with a preferred embodiment of the present invention;

Fig. 2 is a schematic, sectional illustration of a miniature pump, in accordance with an alternative preferred embodiment of the present invention;

Figs. 3A and 3B are schematic, sectional illustrations of a miniature implantable pump, at two different, respective points in a pump cycle thereof, in accordance with another preferred embodiment of the present invention;

Figs. 3C and 3D are schematic, sectional illustrations of a miniature implantable pump, at two different, respective points in a pump cycle thereof, in accordance with still another preferred embodiment of the present invention;

Fig. 4 is a schematic illustration of an inflatable penile prosthesis, operated by a miniature implantable pump, in accordance with a preferred embodiment of the present invention;

Fig. 5 is a schematic illustration of an artificial sphincter valve assembly, operated by a miniature implantable pump, in accordance with a preferred embodiment of the present invention;

Figs. 6A and 6B are schematic illustrations of magnetic drive apparatus, for driving miniature implantable pumps such as are shown in the figures above, in accordance with preferred embodiments of the present invention;

Fig. 7 is a schematic illustration of a magnetic field-responsive element, for driving a miniature implantable pump, in accordance with a preferred embodiment of the present invention;

Figs. 8A and 8B are schematic, sectional illustrations of a miniature implantable pump assembly including a pump and a valve mechanically coupled to the pump, in respective open and closed positions of the valve, in accordance with a preferred embodiment of the present invention;

Fig. 9 is a schematic illustration of an artificial sphincter valve assembly, operated by the pump assembly of Figs. 8A and 8B, in accordance with a preferred embodiment of the present invention; and

Fig. 10 is a schematic, sectional illustration of a miniature implantable pump assembly including a pump and a valve electrically coupled to the pump, in accordance with a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Figs. 1A and 1B, which schematically illustrate a miniature implantable pump 20, in accordance with a preferred embodiment of the present invention. Pump 20 comprises a tubular chamber 22, preferably generally cylindrical, for containing a fluid, which chamber is radially surrounded and defined by an outer wall 24. Chamber 22 has a one-way inlet valve 26 and a one-way outlet valve 28, both of which valves are preferably leaflet valves or alternatively one-way valves of other types known in the art. Wall 24 includes a flexible section 30 to which a magnetic field-responsive element 32, preferably having north and south poles as shown, is mechanically coupled. Wall 24 and section 30 thereof preferably comprise biocompatible plastic materials, wherein section 30 is made of softer and/or thinner material than the remainder of the wall.

Preferably, element 32 comprises a biocompatible ferromagnetic material, such as an alloy of palladium, platinum, cobalt and gallium, or alternatively, an alloy of cobalt, nickel, chromium and molybdenum. Alternatively, element 32 may comprise a magnet made of neodymium iron boron or samarium cobalt, and coated with a biocompatible coating, as described above, or any other suitable magnetic material known in the art, so long as it is biocompatible or treated for biocompatibility.

In other preferred embodiments of the present invention, as will be described below, element 32 may comprise a wire coil.

As illustrated in Fig. 1A, when an external driving magnet 34 is brought into proximity with element 32 in such orientation as to exert a repulsive force thereon, element 32 is urged downward, away from magnet 34. This force will cause flexible section 30 of wall 24 to flex inward, thereby decreasing the volume of chamber 22 and producing an increased pressure in the chamber, which causes outlet valve 28 to open and fluid to flow out therethrough.

As illustrated in Fig. 1B, when magnet 34 is reversed, an attractive force is exerted on element 32, drawing it upward and causing flexible section 30 to flex outward, thereby making chamber 22 expand. Outlet valve 28 closes, inlet valve 26 opens, and fluid is drawn into chamber 22 through the inlet valve as shown. It will thus be appreciated that by alternating the direction of the magnetic field exerted on element 32, for example by rotating driving magnet 34 about an axis 36, an oscillatory force is exerted on element 32. Fluid is pumped through chamber 22 by the resultant alternating expansion and contraction of the chamber.

Preferably, flexible section 30 comprises resilient, elastic material, such as biocompatible rubber, known in the art, which tends to exert a spring-like restoring force when it is stretched. This force, opposite in direction to the force exerted on section 30 by element 32, causes the section to vibrate at a characteristic resonant frequency. Preferably, magnet 34 rotates, or the magnetic field applied to element 32 is otherwise varied, substantially at this resonant frequency, so that the force exerted on element 32 is mechanically amplified to produce relatively large displacements of section 30.

It will be understood that the mutual positioning of element 32 and magnet 34 in Figs. 1A and 1B is shown schematically, by way of example only. Other geometrical configurations of element 32 and magnet 34, as well as other methods of generating a time-varying magnetic field in the vicinity of element 32, as are known in the art, may similarly be used. Several such alternative configurations are described below.

Fig. 2, for example, illustrates schematically an alternative preferred embodiment of the present invention in which magnetic field-responsive element 32 comprises a ring of magnetostrictive material, as is known in the art, substantially surrounding chamber 22. Application of an oscillatory magnetic field causes element 32 to alternately contract and expand, thereby decreasing and increasing the volume of the chamber.

Figs. 3A and 3B illustrate schematically, in sectional view, a miniature implantable pump 40 in accordance with an alternative preferred embodiment of the present invention. Pump 40 comprises a generally tubular outer sleeve 42, which is preferably substantially cylindrical, but may alternatively have any other suitable cross-sectional profile. Sleeve 42 encloses and defines a pump chamber 44, which is bounded axially on one side by a movable plug 46 and on the other side by an outlet valve 48. Plug 46 comprises an annular magnetic field-responsive element 50, which surrounds and defines a central lumen 51, in which an inlet valve 52 is fixed. Inlet valve 52 and outlet valve 48 are preferably leaflet valves or one-way valves of other suitable types known in the art. Element 50 comprises biocompatible magnetic material, which may be of any of the types described above, having north and south poles arranged as shown. Although plug 46 is free to slide axially over a predetermined range of positions inside sleeve 42, the plug fits sufficiently tightly against the inner surface of the sleeve so as to allow fluid contained in the sleeve to flow substantially only through lumen 51, and not around the outside of the plug.

As shown in Fig. 3A, when an external magnetic field, indicated, for example, by magnet 54, is applied in a first direction, generally parallel to axis 56, magnetic force exerted on element 50 urges plug 46 to move in a direction indicated by arrow 58. Preferably an inner stop 53 limits the inward motion of plug 46 in this direction. This motion of plug 46 toward outlet valve 48 produces an increased fluid pressure in chamber 44, thus causing the outlet valve to open as shown, and the volume of fluid in the chamber to be reduced as the fluid flows out through the outlet valve.

Subsequently, as shown in Fig. 3B, magnet 54 is reversed, so as to exert an attractive force on element 50 and draw plug 46 back in a direction indicated by arrow 60. Preferably an outer stop 55 limits the outward motion of plug 36 in this direction. The fluid pressure in chamber 44 drops, causing outlet valve 48 to close and inlet valve 52 to open, and fluid to flow into the chamber. By repeatedly varying the direction of the external magnetic field, preferably in an oscillatory manner, fluid is pumped through pump 40.

In order to amplify the motion of plug 46 relative to the magnetic force applied to element 50, the plug is preferably mounted to the inner surface of sleeve 42 or to stops 53 and

55 by elastic mounting members 57 having a resonant oscillation frequency, as described above. The direction of the magnetic field is varied substantially at the resonant frequency of the mounting members. Members 57 are shown to comprise miniature springs in Figs. 3A and 3B, but may also include, for example, a flexible, elastic diaphragm around the outer edge of the plug or other elastic elements known in the art.

As illustrated in Figs. 3C and 3D, in an alternative preferred embodiment of the present invention, pump 41 has inlet one-way flap valves 52 disposed radially about chamber 44, rather than axially as shown in Figs. 3A and 3B. In this case, plug 46 is entirely closed and separate from the valves, and magnetic field-responsive element 63, contained in the plug, may fill substantially the entire volume of the plug. In other respects, pump 41 is substantially similar in structure and function to pump 40, shown in Figs. 3A and 3B.

Thus, as shown in Fig. 3C (similar to Fig. 3A), plug 46 is urged by the field of magnet 54 in the direction indicated by arrow 58, engaging inner stop 53. As plug 46 moves in this direction, increasing fluid pressure in chamber 44 causes flap valves 52 to close, and the valves are held closed as long as plug 46 is in a position that is axially adjacent to the valves. The increasing fluid pressure causes outlet valve 48 to open, so that fluid may flow therethrough out of chamber 44.

As shown in Fig. 3D (similar to Fig. 3B), when the field of magnet 54 is reversed, plug 46 is urged in the direction indicated by arrow 60, engaging outer stop 55, which may in this case close off entirely the end of sleeve 42. As plug 46 moves in this direction, fluid pressure in chamber 44 decreases, causing outlet valve 48 to close and inlet valves 52 to open, so that fluid flows radially inward into the chamber.

It will be appreciated that in other preferred embodiments of the present invention, not shown in the figures, the movable plug described above may contain the outlet valve, rather than inlet valve 52 as shown in Figs 3A and 3B. Alternatively, one or more outlet valves, for example, outwardly-opening one-way flap valves, may be radially disposed about the chamber, and the movable plug, preferably entirely closed, may cause the outlet valves to operate in a manner analogous to that of inlet valves 52 in Figs. 3C and 3D.

In preferred embodiments of the present invention, pump 20, pump 40, pump 41 or another miniature, magnetically-driven implantable pump, as will be described below, for example, is used to transfer fluid from a low-pressure reservoir, communicating with the pump's inlet valve, to a high-pressure reservoir, communicating with the outlet valve. Two illustrative examples of such transfer are described here.

Fig. 4 illustrates schematically an inflatable penile prosthesis 61, which is inflated by the action of pump 40, shown in Figs. 3A and 3B and described above with reference thereto. Prosthesis 61 is surgically implanted in penis 62 of a subject suffering from impotence, as an aid in producing penile erection. A low-pressure reservoir 64, containing a suitable pump fluid, such as water, is implanted in the abdomen 66 or other suitable location.

When the subject wishes his penis 62 to be erect, he brings a hand-held actuator 68 into proximity with the base of his penis, adjacent to pump 40. Actuator 68 generates an oscillatory magnetic field, as indicated by magnet 54 in Figs. 3A and 3B, thereby operating pump 40 to pump fluid from reservoir 64 into prosthesis 61, thus inflating the prosthesis and erecting penis 62.

Thereafter, to return the penis to its normal, non-erect form, the subject may open a relief valve 70, as is known in the art, preferably by manual pressure thereon. Fluid flows back from prosthesis 61 through a shunt tube 72 into reservoir 64, until the pressures in the prosthesis and the reservoir are equalized.

Fig. 5 schematically illustrates another preferred embodiment of the present invention, in which an implantable, inflatable artificial urinary sphincter 80 is operated by pump 20, as shown in Figs. 1A and 1B and described above. Sphincter 80 preferably comprises a cuff 81, together with pump 20 and a pressure regulating chamber 82, in fluid communication with cuff 81 via a large-diameter tube 86. The sphincter is preferably implanted in the abdomen of a subject, so that cuff 81 surrounds a portion of the subject's urethra 84. Sphincter 80 is intended for use by subjects who due to inadequate function of or control over their natural sphincter valves, are unable to maintain urinary continence without assistance.

Tube 86 includes a valve 88, which is normally open, so that cuff 81 and chamber 82 are maintained at substantially equal fluid pressures. This fluid pressure may range from 0 to approximately 80 cm of water, and is normally preferably in the range of 20-30 cm of water, which is sufficient to compress and close off urethra 84 and prevent accidental urine leakage under normal conditions of intravesical pressure. Chamber 82 is preferably implanted adjacent to the subject's bladder, so that when the subject's intra-abdominal or intravesical pressure increases for any reason, the pressure in chamber 82 similarly increases, thereby causing the pressure in cuff 81 to increase by a substantially equal amount, preferably up to a maximum pressure of 80 cm of water. Such pressure increases are preferably accompanied by the flow of a volume of fluid in the range of 0.1 to 1 cc from chamber 82 through tube 86 and into cuff 81.

Thus, the pressure exerted on urethra 84 by cuff 81 is generally low enough so as to allow an adequate blood supply to reach the urethra and prevent tissue damage that may result when the blood supply is compromised. Cuff 81 automatically increases the pressure on urethra 84 when necessary, however, to prevent urine leakage therethrough urethra 84 due to transient phenomena, such as straining or laughing.

When the subject wishes to urinate, he or she closes valve 88 and actuates pump 20, to pump fluid out of cuff 81 and reduce the pressure in the cuff so that urine may flow through urethra 84. To drive pump 20, an actuator, not shown in Fig. 5, which exerts an oscillatory magnetic field, like the field generated by magnet 34 in Figs. 1A and 1B, is brought into proximity with magnetic element 32 of pump 20, in an appropriate orientation. Preferably, valve 88 is similarly magnetically actuated, for example as described in the above-mentioned PCT

publication WO95/29716. A rotary vane pump, for example, as is described below or in the PCT publication, or a suitable pump of another type known in the art, may also be used in place of pump 20. The actuator preferably comprises a rotating magnet, like magnet 34 or like those shown below in Figs. 6A and 6B, or as described in the above mentioned PCT publication, and preferably drives both pump 20 and valve 88.

Alternatively, valve 88 may be manually actuated, as is known in the art.

After urination is complete, valve 88 is re-opened and the operation of pump 20 is terminated. The pressure in cuff 81 increases to be substantially equal to the pressure in chamber 82, and urinary continence is restored.

Fig. 6A illustrates schematically a hand-held actuator 90, particularly useful for driving pump 40, as shown in Figs. 3A and 3B, for example, as well as other implantable pumps, in accordance with preferred embodiments of the present invention. Actuator 90 comprises a horseshoe magnet 92, which is mounted to an electric motor 94 so as to rotate about an axis 96 of the magnet passing between poles 98 thereof. Permanent magnets of other shapes may similarly be used in place of horseshoe magnet 92. It will be appreciated that as magnet 92 rotates, an oscillating magnetic field is produced in the area of poles 98, analogous to that indicated by magnet 54 in Figs. 3A and 3B. The frequency of oscillation is controlled by regulating the speed to motor 94.

Fig. 6B illustrates schematically an alternative hand-held actuator 100, in accordance with another preferred embodiment of the present invention. Actuator 100 comprises an electromagnet 102 in place of permanent magnet 92 used in actuator 90. Electromagnet 102 comprises a coil 104, preferably wound around a high-permeability core 106, as is known in the art. Driver circuitry 108 provides an oscillatory electric current to coil 104, so as to create an oscillating magnetic field, which is substantially directed along an axis 110 of the coil. Actuator 100 is useful, for example, in driving pump 20, shown in Figs. 1A and 1B. Preferably, circuitry 108 drives coil 104 at an oscillatory frequency that is substantially equal to the resonant frequency of mechanical vibration of section 30 of the pump, as described above.

Although in the above embodiments of the present invention, magnetic field-responsive elements 32, 50 and 63 are described as comprising permanent magnets, in other preferred embodiments of the present invention, other types of elements are used to produce the volume variation.

Thus, Fig. 7 illustrates schematically a magnetic field-responsive element 120, in accordance with an alternative preferred embodiment of the present invention, which element may be used, for example, in place of element 32, shown in Figs. 1A and 1B. Element 120 comprises a coil 122, which is preferably wound around a high-permeability core 124, as is known in the art. Coil 122 is connected in series with oscillator circuitry 126, comprising, for example, a capacitor of an appropriate value so as to form a resonant circuit. Preferably, the

resonant frequency of this circuit is substantially equal to the frequency of oscillation of an external, driving magnetic field, as described in reference to the preferred embodiments above.

When an external, oscillatory magnetic field is applied to element 120 along axis 128, current is induced to flow in coil 122. As is known in the art, this current generates an induced magnetic field along axis 128, which induced field oscillates at substantially the same frequency as the external field, but is generally 90° out of phase therewith. Interaction of the external magnetic field with the induced magnetic field will exert an oscillatory force on element 120 in the direction of axis 128. Because the force depends on the difference of the external and induced magnetic fields, it oscillates at substantially twice the frequency of oscillation of the external, driving magnetic field. This force causes flexible section 30 of wall 24 to flex in and out, as shown in Figs. 1A and 1B and described with reference thereto. Preferably, the oscillation frequency of the magnetic field is chosen so that section 30 is driven substantially at its resonant vibrational frequency, as described above.

In another preferred embodiment of the present invention, element 120 comprises only core 124, without coil 122 and oscillator circuitry 126, but operates in a substantially similar manner to that described above.

Figs. 8A and 8B are schematic, sectional illustrations showing a magnetically-actuated implantable pump assembly 130, in accordance with another preferred embodiment of the present invention. Pump assembly 130 comprises a rotary-vane turbine pump 134 and a valve 136 coupled to the pump. Both pump 134 and valve 136 are contained within a common envelope 132, having an outlet 133 and an inlet 135. In Fig. 8A, valve 136 is shown in an open position, whereas in Fig. 8B the valve is closed.

Pump 134 comprises rotor vanes 140 mounted externally on a rotatable shaft assembly 138. The shaft assembly is mounted between stators 142 and 143 (wherein the vanes of stator 143 are not shown in the figure for clarity of illustration). Shaft assembly 138 contains a magnet 144, so that when a suitably oriented rotating magnet, such as magnet 34 shown in Figs. 1A and 1B, is brought into proximity with pump assembly 130, the external magnetic field exerts a force on magnet 144, causing shaft assembly 138 to rotate. This system of remote magnetic drive is referred to as sequential pole coupling, and is further described in the above-mentioned PCT patent publication WO95/29716. The operation of pump 134 is substantially similar to that of magnetically-driven pumps described therein. When valve 136 is open, as shown in Fig. 8A, the rotation of rotor vanes 140 pumps a fluid through envelope 132 from inlet 135 to outlet 133. When the external magnet is moved away from assembly 130, or when its rotation is halted, shaft assembly 138 will stop rotating.

Valve 136 opens and closes responsive to the rotation of shaft assembly 138, as described below. The valve comprises a shaft 146, an inertial nut 148, a stop 154 and a plug 156. Shaft 146, having an external thread 150, is coupled to shaft assembly 138 so as to rotate therewith. Nut 148 has an internal thread 152, which receives thread 150 so that the nut can

rotate about and travel longitudinally along the threaded portion of shaft 146. The nut comprises a relatively massive material, for example, stainless steel or titanium, and is shaped so as to have a large rotational moment relative to shaft assembly 138, as illustrated in the figures. As a result, when shaft assembly 138 is rotationally accelerated in a given direction, nut 148 will generally be angularly accelerated in the opposite direction. A rotational deceleration of the shaft assembly will similarly cause a relative angular acceleration of the nut. Plug 156 comprises a flexible, elastic material, for example, silicone rubber, and is coupled to nut 148 by a bearing 158.

To operate pump assembly 130, pump 134 is actuated and rotates in a clockwise direction (viewed from the direction of outlet 133). Because of the large moment of nut 148, the nut does not begin to rotate until threads 150 and 152 are fully engaged, at which point a flange 155 on nut 148 engages one end of stop 154 fixed to stator 143, as shown in Fig. 8A. Thus, plug 156 is kept away from a corresponding inlet opening 160 in envelope 132, so that valve 136 is held open.

When the rotation of shaft assembly 138 is stopped, as described above, the inertia of nut 148 will cause it to continue rotating. Thread 152 will thus longitudinally disengage from thread 150 until flange 155 reaches the other end of stop 154, as shown in Fig. 8B. In this position, plug 156 is pressed against an inner surface of envelope 132, thus sealing opening 160 and closing valve 136, as shown in Fig. 8B. Bearing 158 rotationally decouples plug 156 from nut 148 when the plug engages the envelope.

However, pump assembly may also be operated to leave valve 136 open when pump 134 is not operating: Shaft assembly 138 is rotated briefly in a counterclockwise direction, and is then stopped, as described above. As a result of the rotation and subsequent deceleration of the shaft assembly, nut 148 will rotate counterclockwise until it reaches substantially the position shown in Fig. 8A, where its rotation is halted by flange 155 contacting stop 154.

It will be observed that when the clockwise rotation of shaft assembly 138 is resumed, nut 148 will remain in or travel back to the position shown in Fig. 8A, so that fluid is pumped through valve 136. Thus, the valve is opened and closed automatically, in consonance with the directional actuation and deactuation of pump 134. No additional mechanism or controls are needed to operate the valve beyond the magnetic drive provided for operating the pump.

Fig. 9 is a schematic, partly sectional illustration showing the use of pump assembly 130 in an implantable artificial sphincter assembly 165. It will be observed that assembly 165 is substantially similar to artificial sphincter assembly 80 shown in Fig. 5, except that in assembly 165, pump 134 and valve 136 are connected in series, as part of a single tube connecting cuff 81 and chamber 82, rather than in the shunt configuration of assembly 80. Thus, relative to assembly 80, the construction of assembly 165 is simplified, and no separate control is needed to operate the valve.

Fig. 10 is a schematic, sectional illustration showing a pump assembly 170, in accordance with still another preferred embodiment of the present invention. Like pump assembly 130, assembly 170 comprises a magnetically-driven pump 176 and a valve 178, which is actuated by rotation of the pump.

Pump 176 comprises a magnet 180, mounted on a shaft 182, so as to rotate in response to an externally-applied, time-varying magnetic field, as described above. Shaft 182 is coupled to turn a centrifugal vane pump mechanism 184, so that when valve 178 is open, pump 176 transfers a fluid from an inlet 174 of pump assembly 170, through a fluid channel 186 and out through an outlet 172 of the assembly.

Valve 178, shown in a closed position in Fig. 10, comprises a low-coercivity magnetic disk 196, preferably comprising silicon steel, attached to a plug 197, which plugs a hole 198 through which fluid passes between channel 186 and outlet 172. The valve is operated by transfer of electrical energy from pump 176. When magnet 180 rotates, an AC electrical current is generated in a coil 188 that surrounds the magnet. Coil 188 is coupled to a switched rectifier 190, preferably comprising a bridge rectifier, as is known in the art, which receives and rectifies the AC current from coil 188. Rectifier 190 produces a DC current in a coil 192, wound around a ferromagnetic core 194, wherein the direction of the DC current is switched responsive to an external signal, as described below. When the DC current flows through coil 192 in a first direction, for example, clockwise as seen from outlet 172, a magnetic field along the axis of the coil attracts and magnetizes disk 196, so that plug 197 plugs hole 198, closing valve 178. When the DC current is reversed, disk 196 is demagnetized, so that hole 198 is unplugged, and the valve is opened. A spring fixed between core 194 and disk 196 (not shown in the figures) may be used to repel the disk away from the core when the disk is demagnetized.

The direction of the DC current produced by switched rectifier 190 in coil 192 is preferably switched by a miniature solid-state switch (not shown in the figures), as is known in the art, coupled to the rectifier. The switch is preferably actuated by an external signal, for example, an RF pulse of predetermined frequency and duration. Alternatively, the switch may be actuated by a change in the speed of rotation of magnet 180. Such a change may be induced, for example, by varying the speed of an external rotating magnet driving the rotation of magnet 180, such as magnet 34 (Figs. 1A and 1B).

It will be appreciated that pump assembly 170 may be used in conjunction with artificial sphincter 165, shown in Fig. 9, in place of pump assembly 130. Similarly, pump assemblies 130 and 170 may be used in conjunction with penile prosthesis 61, shown in Fig. 4, as well as with other types of inflatable prosthetic devices known in the art. Pump assemblies 130 and 170 differ from other embodiments of the present invention described herein, as well as from implantable pumps known in the art, in that they include both a pump and a valve in a single assembly, powered by a single power source, preferably external to the body, and under common control.

It will be appreciated that the preferred embodiments described above are cited by way of example, and the full scope of the invention is limited only by the claims.

CLAIMS

1. Pump apparatus operated by remote energy transfer, for implantation in the body of a subject, said apparatus comprising:

a pump chamber having an inlet and an outlet, and comprising an exterior wall, which defines and contains a volume of a fluid therein;

a one-way inlet valve at the inlet of the chamber;

a one-way outlet valve at the outlet of the chamber; and

a magnetic field-responsive element, coupled to the chamber, such that movement of the element in response to application of a magnetic field thereto causes the volume of fluid in the chamber to change.

2. Apparatus according to claim 1, wherein movement of the element in a first direction causes the volume to increase, and movement of the element in a second direction, generally opposite to the first direction, causes the volume to decrease.

3. Apparatus according to claim 2, wherein movement of the element in the first direction causes the inlet valve to open and the outlet valve to close, so that fluid flows into the chamber, and movement of the element in the second direction causes the inlet valve to close and the outlet valve to open, so that fluid flows out of the chamber.

4. Apparatus according to any of the preceding claims, wherein the inlet and outlet valves comprise leaflet valves.

5. Apparatus according to any of the preceding claims, and having a resonant mechanical frequency with respect to movement of the element.

6. Apparatus according to claim 5, wherein the element comprises a magnetic field-responsive circuit having a resonant oscillation frequency approximately equal to half the resonant mechanical frequency.

7. Apparatus according to any of the preceding claims, wherein the wall comprises resilient material.

8. Apparatus according to any of the preceding claims, wherein at least a portion of the wall flexes in response to movement of the element.

9. Apparatus according to claim 8, wherein the chamber is generally tubular in form, having an axis generally defined by the long dimension of the chamber, with the inlet and outlet valves disposed axially at opposite ends of the chamber, and wherein the element is coupled radially to the portion of the wall that flexes.

10. Apparatus according to claim 9, wherein in response to application of the magnetic field to the element in a first field direction, the element causes the portion of the wall to flex radially outward, and in response to application of the magnetic field in a second field direction,

generally opposite to the first field direction, the element causes the portion of the wall to flex radially inward.

11. Apparatus according to claim 10, wherein the first and second field directions are generally perpendicular to the axis of the chamber.

12. Apparatus according to any of claims 1-7, wherein the wall of the chamber comprises a generally tubular sleeve, having an axis generally defined by the long dimension of the sleeve, one of the ends of which is closed by an axially movable plug, to which the element is coupled.

13. Apparatus according to claim 12, wherein the element is contained in the plug.

14. Apparatus according to claim 12 or 13, wherein the plug contains at least one of the inlet and outlet valves.

15. Apparatus according to any of claims 12-14, wherein the plug is coupled to the sleeve by an elastic mounting member.

16. Apparatus according to any of claims 12-15, wherein in response to application of the magnetic field to the element in a first field direction, the element causes the plug to move axially outward, and in response to application of the magnetic field in a second field direction, generally opposite to the first field direction, the element causes the plug to move axially inward.

17. Apparatus according to claim 16, wherein the first and second field directions are generally parallel to the axis of the sleeve.

18. Apparatus according to any of the preceding claims, wherein the element comprises a conductive coil.

19. Apparatus according to any of the preceding claims, wherein the element comprises a permanent magnet.

20. Apparatus according to any of the preceding claims, wherein the element comprises ferromagnetic material.

21. Apparatus according to any of the preceding claims, wherein the element comprises magnetostrictive material.

22. Pump apparatus operated by remote energy transfer, for implantation in the body of a subject, said apparatus comprising:

a pump chamber having an inlet and an outlet;

a pump mechanism within the chamber, which pumps a fluid from the inlet to the outlet;

a magnetic field-responsive element, coupled to drive the pump mechanism responsive to application of a magnetic field thereto; and

a valve, which is driven by the pump mechanism to control the flow of the fluid through the pump chamber.

23. Apparatus according to claim 22, wherein the magnetic field-responsive element comprises a magnet driven by the magnetic field by sequential pole coupling.

24. Apparatus according to claim 22 or 23, wherein the pump mechanism comprises a rotary mechanism.

25. Apparatus according to claim 24, wherein the rotary pump mechanism comprises a turbine pump.

26. Apparatus according to claim 24, wherein the rotary pump mechanism comprises a centrifugal pump.

27. Apparatus according to any of claims 24-26, wherein the valve is mechanically coupled to the pump mechanism.

28. Apparatus according to claim 27, wherein the pump mechanism comprises a rotary shaft having a longitudinal axis, and wherein the valve comprises a plug, which moves longitudinally along the axis to open and close a valve opening, responsive to rotation of the shaft.

29. Apparatus according to claim 28, wherein the plug is coupled to an inertial element, which is coupled to the shaft so as to rotate thereabout.

30. Apparatus according to claim 29, wherein the shaft includes a threaded portion, and wherein the inertial element comprises a nut, which travels longitudinally along the threaded portion of the shaft.

31. Apparatus according to claim 30, and comprising a stop, which stops the travel of the nut in at least one of a closed and an open position of the valve.

32. Apparatus according to any of claims 24-26, wherein the valve is electrically coupled to the pump mechanism.

33. Apparatus according to claim 32, and comprising a generating coil associated with the magnetic field-responsive element, which generates an electrical current for operating the valve.

34. Apparatus according to claim 33, and comprising a rectifier, which rectifies the current generated by the generating coil.

35. Apparatus according to claim 33 or 34, wherein the valve comprises an electromagnet, which is powered by the electrical current generated by the generating coil.

36. Apparatus according to claim 35, wherein the valve comprises an opening and a plug received by the opening, and wherein the plug comprises a magnetic material, such that the valve opens and closes by movement of the plug relative to the opening, responsive to a magnetic field produced by the electromagnet.

37. Apparatus according to claim 36, wherein the magnetic material is magnetized and demagnetized by the magnetic field produced by the electromagnet.

38. Apparatus according to claim 37, wherein the magnetic material comprises silicon steel.

39. Apparatus according to any of claims 35-38, wherein the electromagnet comprises a coil wound around a ferromagnetic core, and wherein the valve opens and closes responsive to the direction of flow of an electrical current in the coil.

40. Apparatus according to claim 39, wherein the direction of flow of the current in the coil is switched responsive to a change in a speed of movement of the magnetic field-responsive element.

41. Apparatus according to any of the preceding claims, and comprising a hand-held magnetic actuator, which generates a time-varying magnetic field outside the body.

42. Apparatus according to claim 41, wherein the actuator comprises a rotating magnet.

43. Apparatus according to claim 42, wherein the rotating magnet defines a plane and rotates about an axis substantially parallel to the plane and passing between the poles of the rotating magnet.

44. Apparatus according to any of claims 41-43, wherein the actuator comprises an electromagnet.

45. Apparatus according to any of the preceding claims, and comprising a low-pressure reservoir communicating with the inlet of the pump chamber and a high-pressure reservoir communicating with the outlet of the pump chamber, wherein the apparatus transfers fluid from the low-pressure to the high-pressure reservoir.

46. Apparatus according to claim 45, wherein transfer of fluid to the high-pressure reservoir inflates the high-pressure reservoir.

47. Apparatus according to claim 46, wherein the high-pressure reservoir is implanted in the penis of a subject, and wherein inflation of said reservoir causes it to become rigid, thereby producing an erection of the penis.

48. Apparatus according to any of claims 1-44, for implantation in the abdomen of a subject, and comprising:

a cuff, filled with a fluid, communicating with the inlet of the pump chamber, which cuff substantially surrounds the urethra; and

a pressure-responsive regulator chamber, communicating with the outlet of the pump chamber,

wherein pressure of the fluid in the cuff restricts urinary flow through the urethra, and

wherein the pump operates to transfer the fluid from the cuff to the chamber, such that the pressure exerted by the cuff on the urethra decreases, allowing urine to flow through the urethra.

49. An artificial urinary sphincter for implantation in the abdomen of a subject, to control urinary flow through the subject's urethra, comprising:

a cuff, filled with a fluid, which cuff substantially surrounds and exerts pressure on the urethra, so as to restrict urinary flow therethrough;

a tube, containing a valve and having first and second ends, wherein the first end is in fluid communication with the cuff;

a pressure-responsive regulator chamber, in fluid communication with the second end of the tube, such that when the valve is open, pressure exerted on the chamber causes a corresponding pressure to be exerted by the cuff on the urethra; and

a miniature pump, connected between the cuff and the regulator chamber, so as to pump the fluid from the cuff to the chamber, in order to reduce the pressure exerted by the cuff and allow urine to pass through the urethra.

50. Apparatus according to claim 49, wherein the pump is actuated by a magnetic field produced outside the subject's body.

51. Apparatus according to claim 49 or 50, wherein the pump and the valve are connected between the cuff and the chamber in parallel.

52. Apparatus according to claim 49 or 50, wherein the pump and the valve are connected between the cuff and the chamber in series.

53. Apparatus according to any of claims 48-52, wherein when the pump is not operating, the cuff and the regulator chamber are maintained at substantially equal pressures by fluid flow therebetweeen.

54. Apparatus according to claim 53, wherein the pressures in the regulator chamber and the cuff increase responsive to an increase in pressure in the subject's bladder.

55. A method for pumping a fluid from a source location to a receiving location inside the body of a subject, said method comprising:

coupling a magnetic field-responsive element to an implantable pump chamber characterized by a variable volume and having one-way inlet and outlet valves, so that oscillatory movement of the element causes the volume of the chamber to alternately increase and decrease;

implanting the chamber and the element inside the body, wherein the inlet and outlet valves are in fluid communication with the source and receiving locations, respectively; and

applying a cyclically time-varying magnetic field to the element, causing oscillatory movement of the element, which causes the fluid to be pumped through the chamber from the source to the receiving location.

56. A method according to claim 55, wherein the chamber and the element are jointly characterized by a resonant frequency, and wherein applying the magnetic field to the element

comprises applying an oscillatory magnetic field having an oscillation frequency that is substantially dependent on the resonant frequency.

57. A method according to claim 56, wherein the oscillation frequency is generally equal to the resonant frequency.

58. A method according to claim 56, wherein the oscillation frequency is generally equal to half the resonant frequency.

59. A method according to any of claims 55-58, wherein applying the cyclically varying magnetic field comprises alternately applying the field in a first direction, which causes the volume of the chamber to increase, so that fluid is drawn into the chamber through the inlet valve, and applying the field in a second direction, generally opposite to the first direction, which causes the volume of the chamber to decrease, so that fluid is ejected from the chamber through the outlet valve.

60. A method according to claim 59, wherein the pump chamber has an axis defined by a long dimension thereof, and wherein the first and second directions are generally parallel to the axis.

61. A method according to claim 59, wherein the pump chamber has an axis defined by a long dimension thereof, and wherein the first and second directions are generally perpendicular to the axis.

62. A method for pumping a fluid from a source location to a receiving location inside the body of a subject, said method comprising:

coupling a magnetic field-responsive element to a rotary pump mechanism in an implantable pump chamber having an inlet and an outlet, so that rotation of the element causes the fluid to be pumped through the chamber;

coupling a valve to the pump mechanism so as to open and close responsive to energy received by the valve from the pump mechanism;

implanting the chamber inside the body, such that the inlet and outlet are in fluid communication with the source and receiving locations, respectively; and

applying a cyclically time-varying magnetic field to the element, causing rotation of the element, which opens the valve and causes the fluid to be pumped through the chamber from the source to the receiving location.

63. A method according to claim 62, and comprising altering the time-varying magnetic field applied to the element, causing a change in the rotation of the element, which closes the valve.

64. A method according to claim 63, wherein causing the change in the rotation of the element comprises stopping the rotation.

65. A method according to claim 63 or 64, wherein causing the change comprises removing the time-varying magnetic field applied to the element.

66. A method according to any of claims 62-65, wherein coupling the valve to the pump mechanism comprises mechanically coupling the valve to the pump mechanism.

67. A method according to any of claims 62-65, wherein coupling the valve to the pump mechanism comprises electrically coupling the valve to the pump mechanism.

68. A method according to any of claims 55-67, wherein applying the magnetic field comprises rotating a magnet about an axis passing between north and south poles thereof, and bringing the magnet into proximity with the element.

69. A method according to any of claims 55-68, wherein applying the magnetic field comprises applying an oscillatory electrical current to a coil, and bringing the coil into proximity with the element.

70. A method for treatment of urinary incontinence in a subject, comprising:

coupling an fluid-filled cuff to a pressure-responsive chamber;

connecting a miniature pump between the cuff and the chamber, so that when the pump is actuated, it pumps fluid from the cuff to the chamber;

implanting the cuff around the urethra of the subject, so as to exert pressure on the urethra and thus restrict urine flow therethrough;

implanting the chamber and pump in the abdomen of the patient, with the chamber adjacent to the urinary bladder, such that the pressure in the chamber increases in response to a transient increase in pressure in the bladder, causing fluid to flow from the chamber, through the tube and into the cuff, thus increasing the pressure exerted by the cuff on the urethra, so as to prevent leakage of urine through the urethra; and

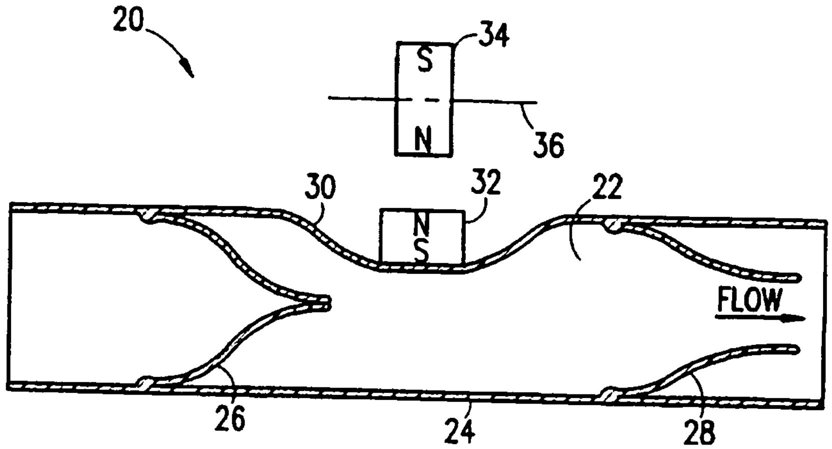
actuating the pump to reduce the pressure in the cuff and thus to allow urination.

71. A method according to claim 70, wherein the pump comprises a magnetic-field responsive element, and wherein actuating the pump comprises applying a magnetic field outside the body of the subject, so as to transfer energy to the magnetic-field responsive element.

72. A method according to claim 70 or 71, and comprising closing a valve between the chamber and the cuff, so as to prevent the flow of fluid from the chamber to the cuff.

73. A method according to claim 72, wherein connecting the pump comprises connecting the pump in a shunt configuration with respect to the valve.

74. A method according to any of claims 70-72, where connecting the pump comprises connecting the pump in series with the valve.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N
36
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S
22
FLOW
26
24
28

FIG. 1A

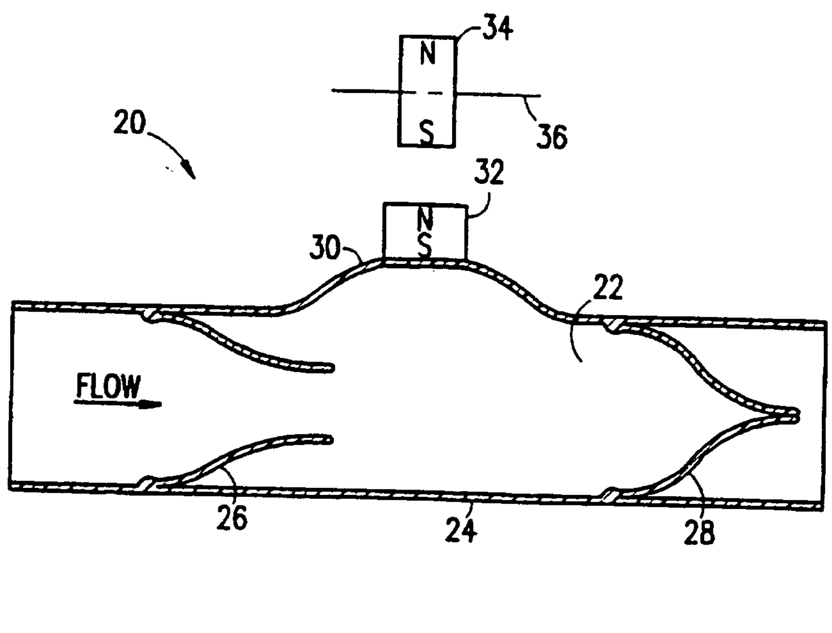
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FIG. 1B

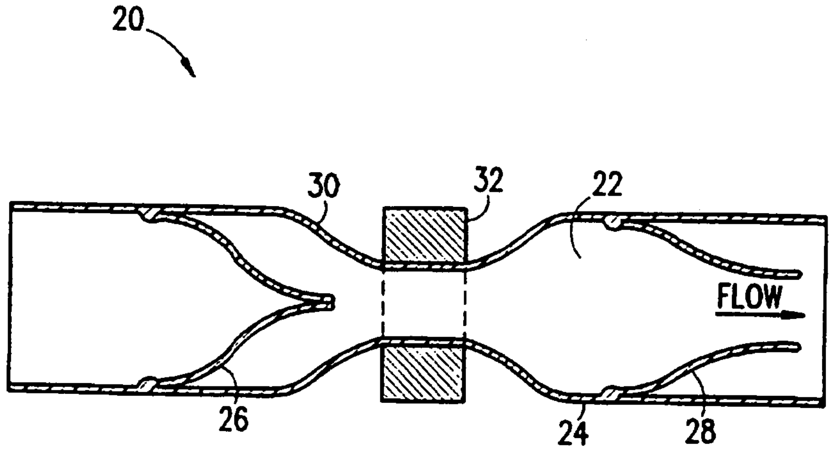

FIG. 2

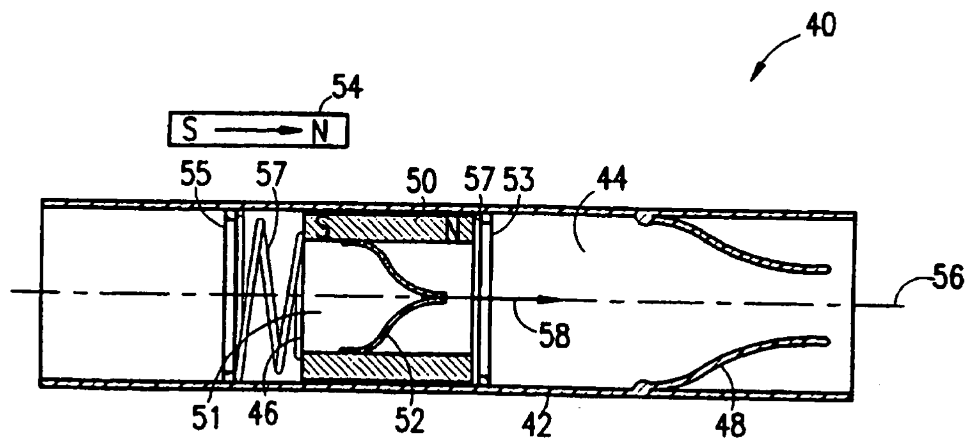
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FIG. 3A

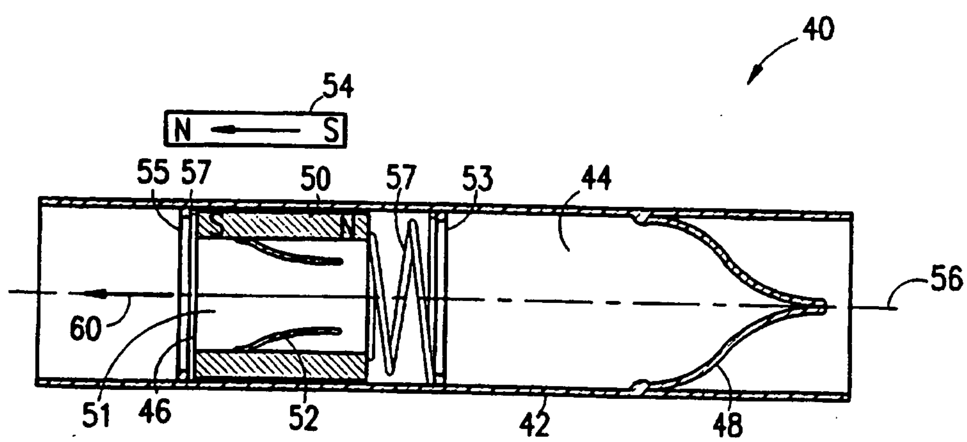
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FIG. 3B

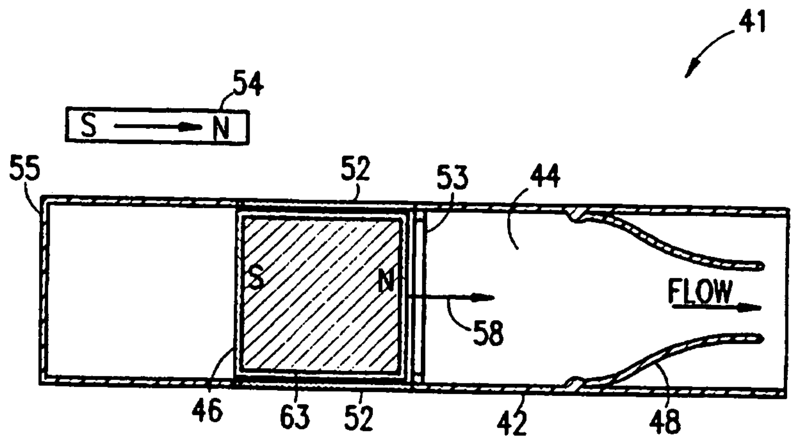
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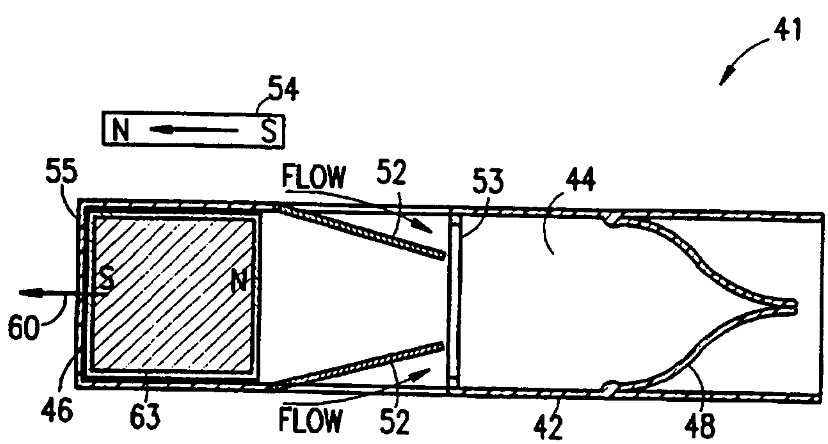
FIG. 3C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48

FIG. 3D

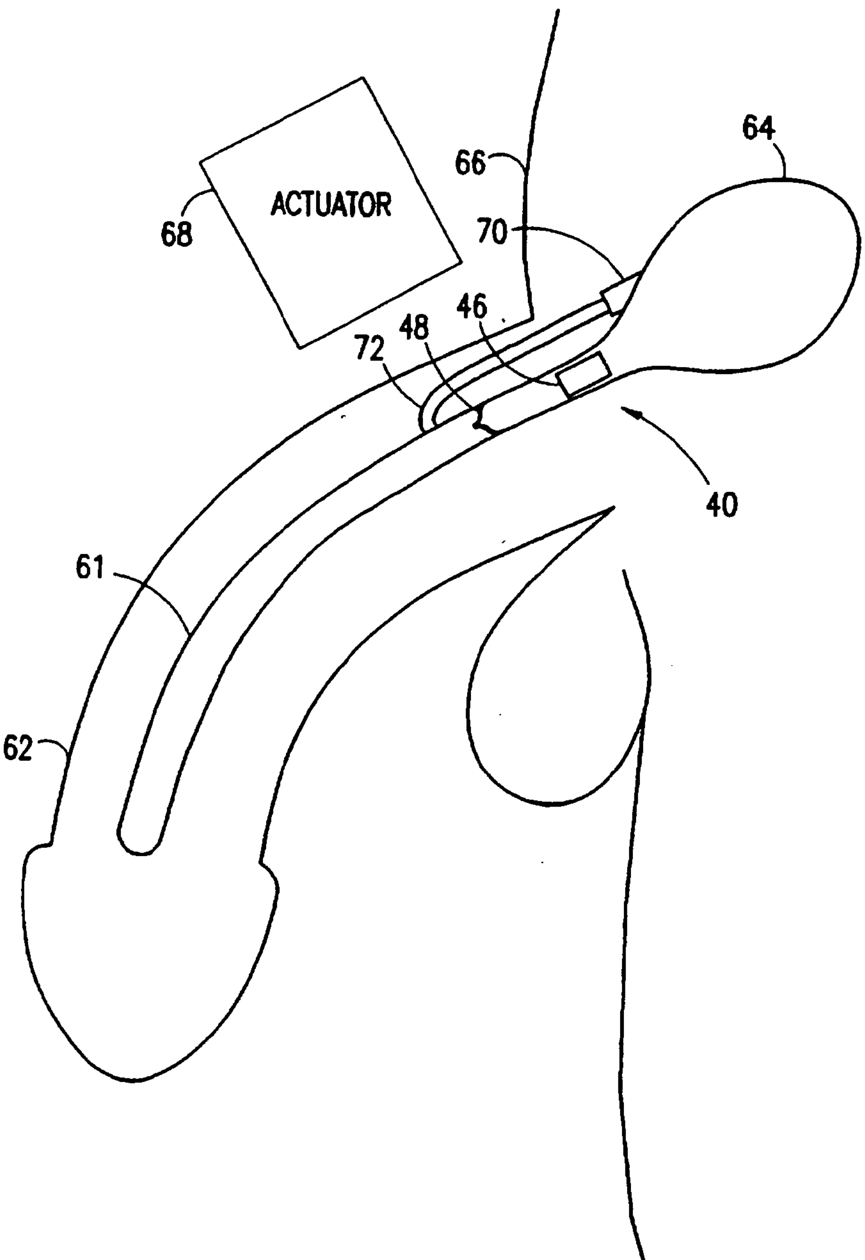

FIG. 4

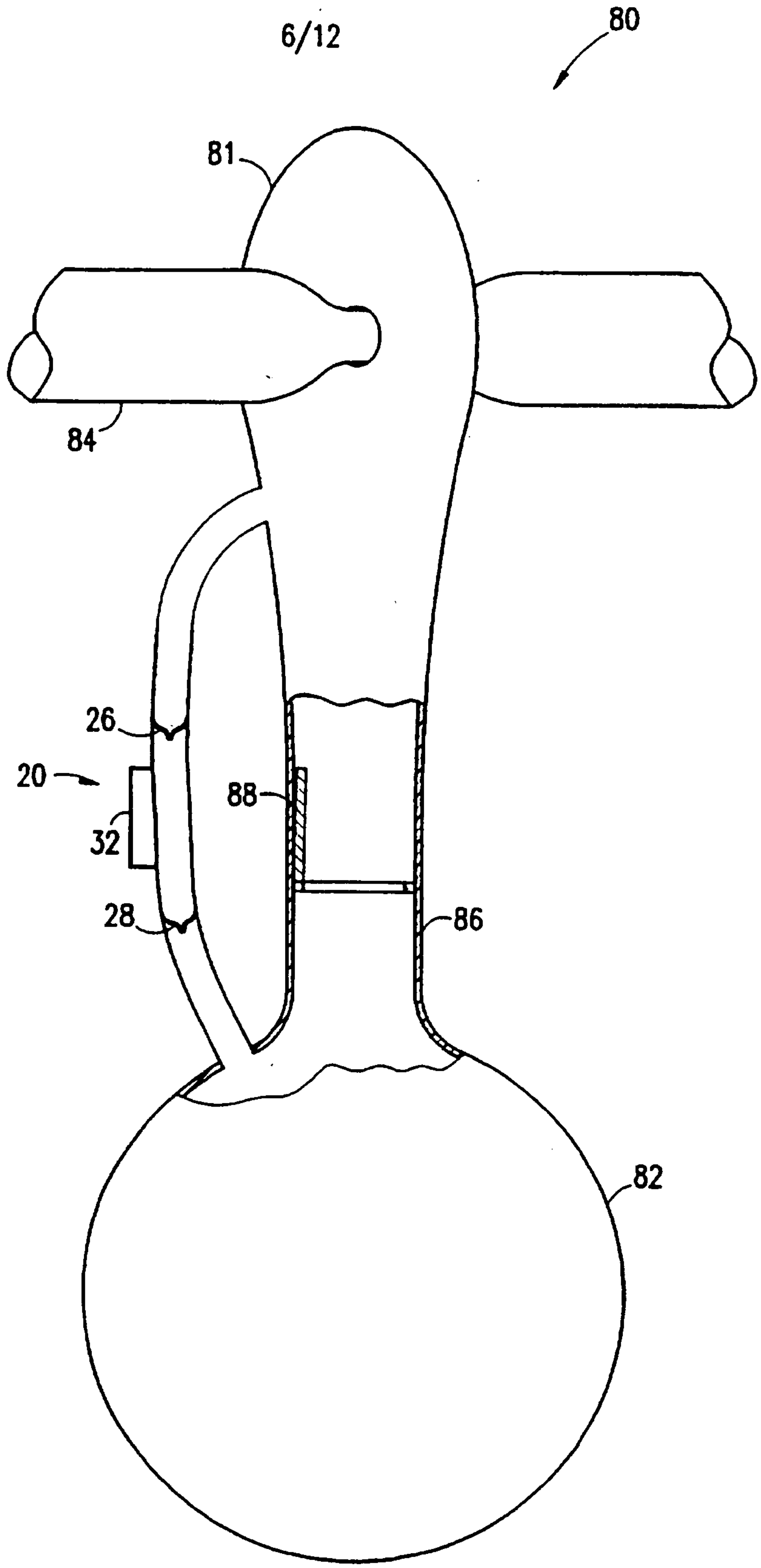

FIG. 5

FIG. 6A

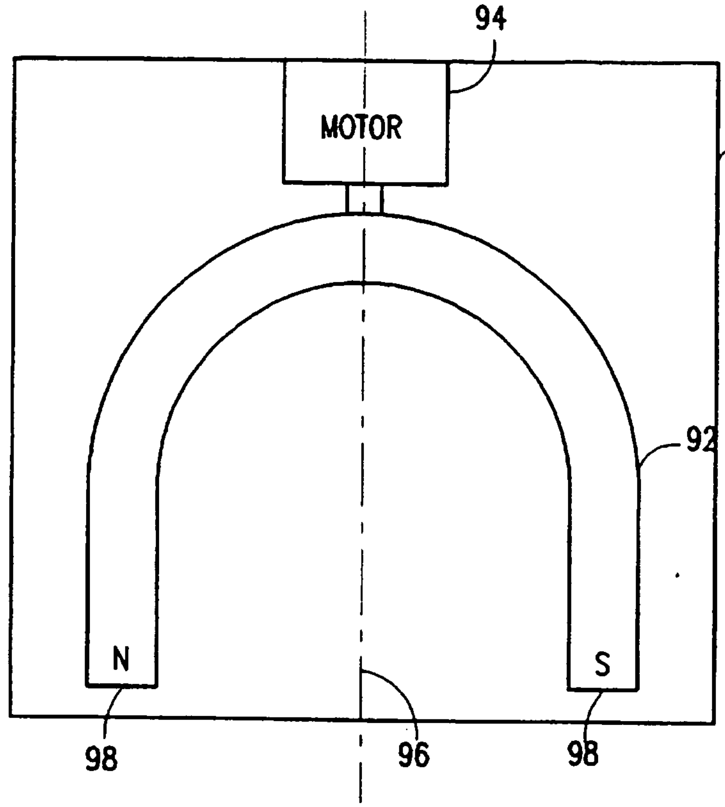
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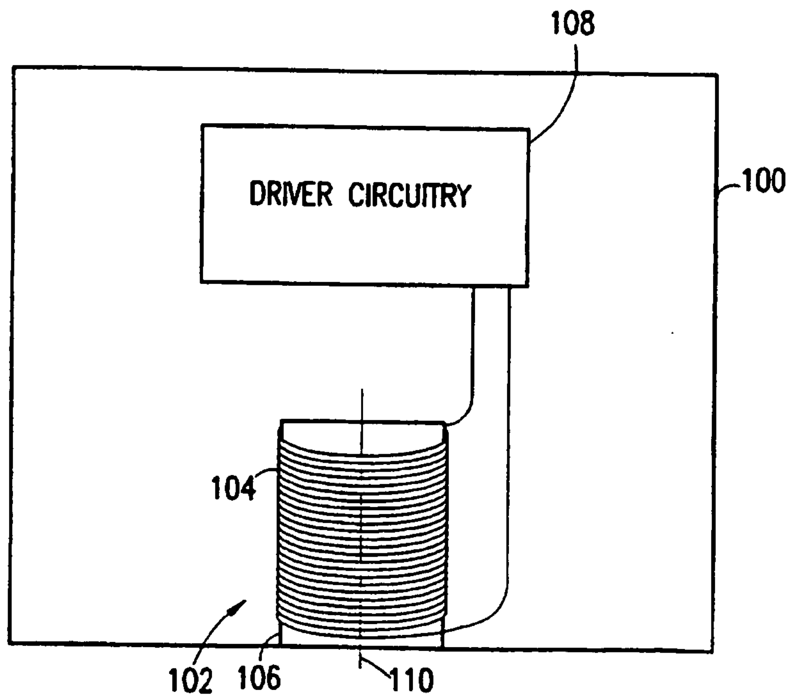
FIG. 6B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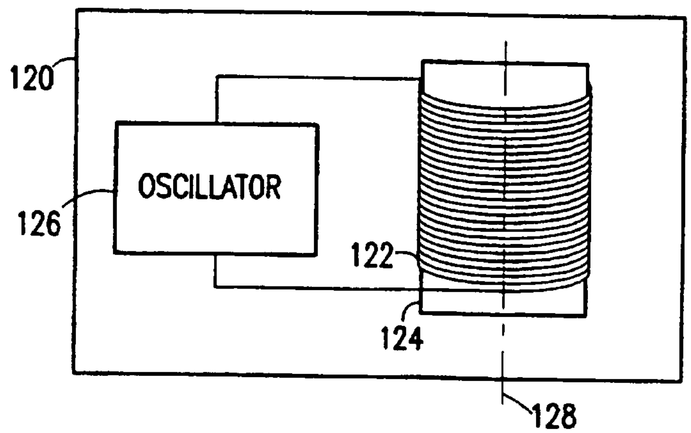
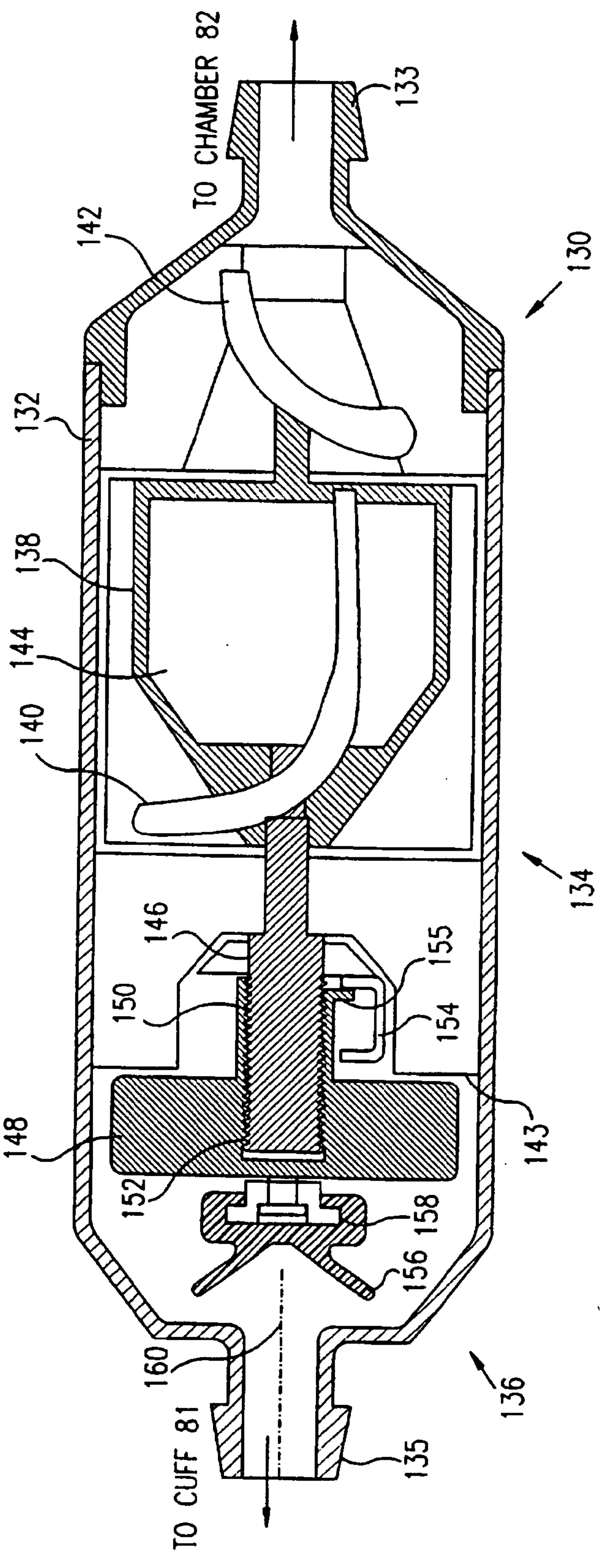


FIG. 7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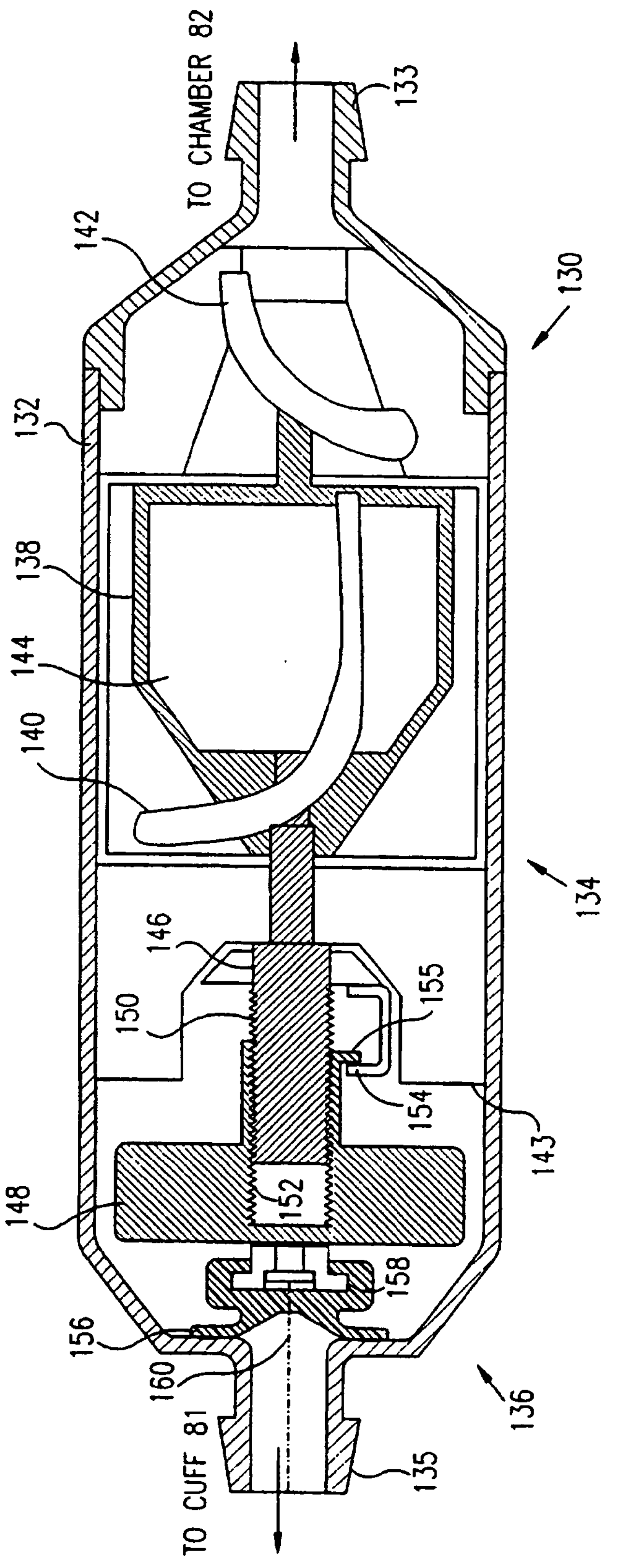
TO CUFF 81

FIG. 8A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TO CUFF 81
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FIG. 8B

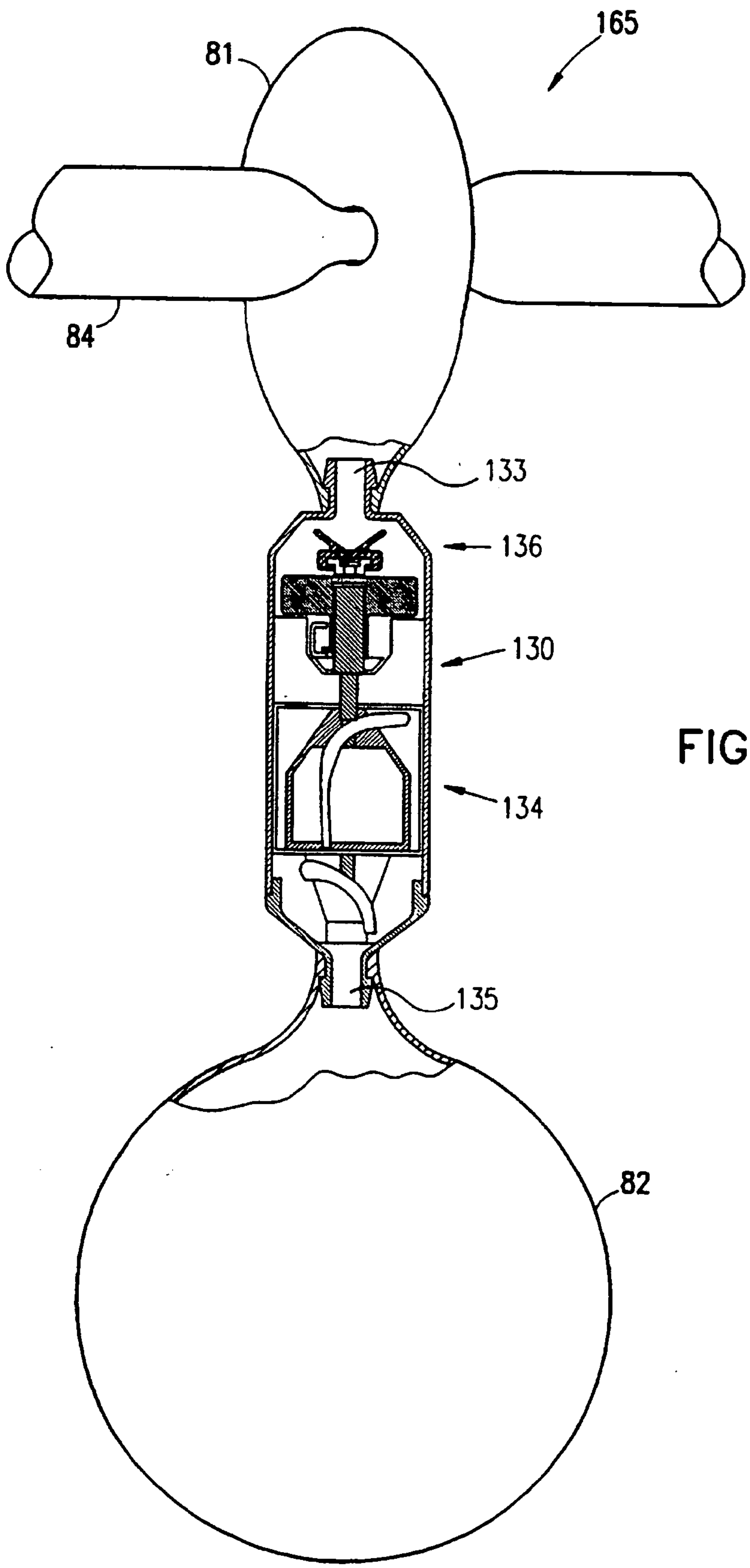
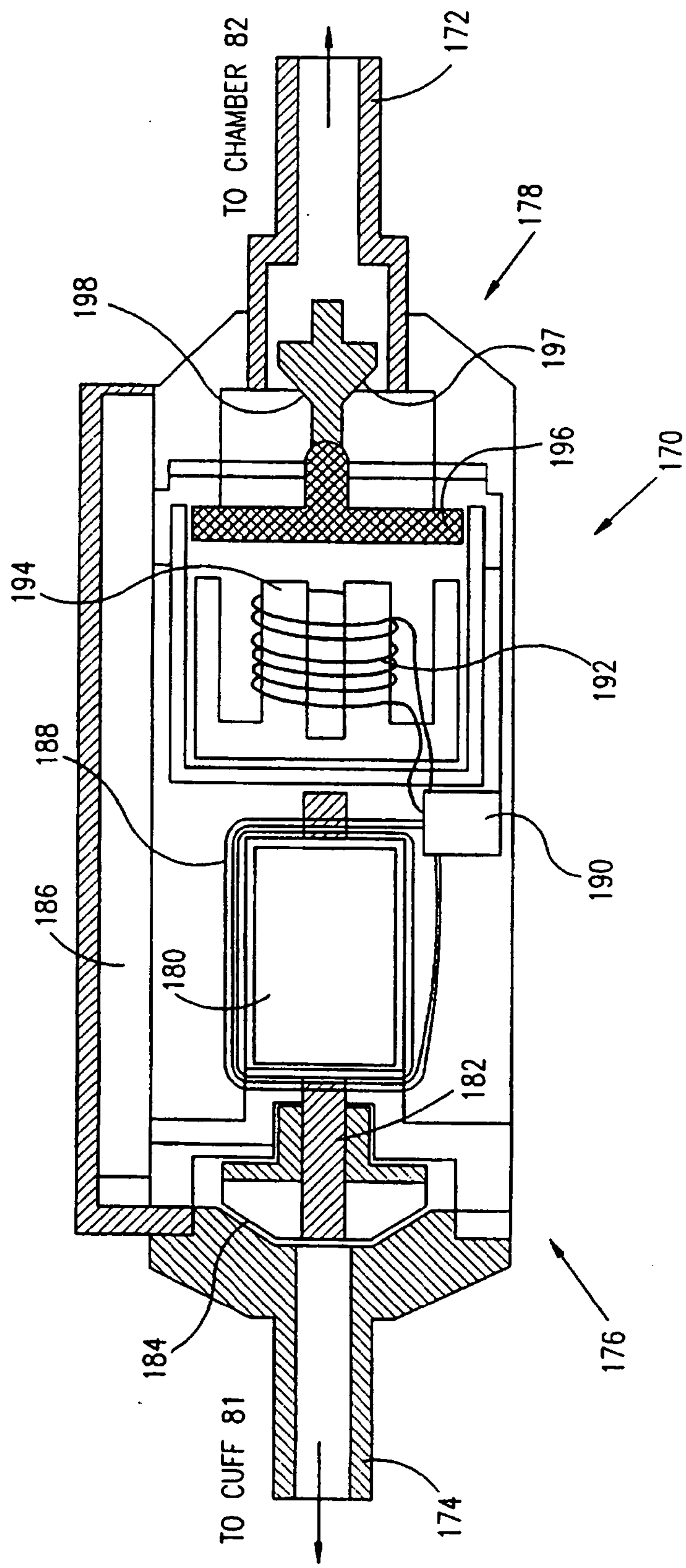


FIG. 9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184
176
TO CUFF 81
174

FIG. 10

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 97/00145

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 29716 A (INFLUENCE INC) 9 November 1995 cited in the application see the whole document	1-21
A	US 5 437 605 A (HELMY ALI M) 1 August 1995 cited in the application see column 3, line 58 - column 6, line 53; figures 1-6	22-48
A	US 3 750 194 A (SUMMERS G) 7 August 1973 see abstract; figures	49-54
A	US 4 498 850 A (PERLOV GENA ET AL) 12 February 1985 see column 1, line 45 - column 2, line 42 see column 4, line 8 - column 10, line 37; claims; figures 1-10	55-69

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

2

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 1997	15.09.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Sánchez y Sánchez, J

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Internati Application No
PCT/IL 97/00145

C.(Continuation) D CUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 941 461 A (FISCHELL ROBERT E) 17 July 1990 cited in the application see column 2, line 36 - column 4, line 51; figures 1-6 ---	1
A	FR 2 251 302 A (ANVAR) 13 June 1975 -----	

2

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int ...tional application No.
PCT/IL 97/00145

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 70-74
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(iv) PCT

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Internat. Application No
PCT/IL 97/00145

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9529716 A	09-11-95	AU 2464695 A EP 0758254 A	29-11-95 19-02-97
US 5437605 A	01-08-95	CA 2124398 A EP 0626154 A JP 8107907 A	28-11-94 30-11-94 30-04-96
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US 4941461 A	17-07-90	NONE	
FR 2251302 A	13-06-75	NONE	